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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,607	03/01/2002	Teresa Aja	480140.476	7928

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 6300  
SEATTLE, WA 98104-7092

EXAMINER

SALIM, ALI REZA

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/01/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/087,607

Applicant(s)

AJA ET AL.

Examiner

A R Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/13/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Response to Amendment***

The receipt of preliminary amendment of 10/2/2003, is acknowledged. Claims 10, 11 have been canceled. Claims 1-9, 12-17 are pending before the examiner.

### ***Election/Restrictions***

Applicant's election without traverse of Group II (claims 1-9, 12-17) in the reply filed on 10/2/2003 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

Claims 1-9, 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of "anti-apoptotic reagent", the intended "reagent" is not defined, and the intended metes and bound of the "reagent" is not known. In addition, the claim is indefinite for recitation of "at least a portion of which is suspected of being virally infected", how is this determined? How can one determines this, is a virus that exhibits latent behavior also intended? The claim has been interpreted in light of the specification and since the specification does not provide adequate teaching for the broad recitation of claim, the claim is vague and indefinite. This affects the dependent claims.

### ***Claim Rejections - 35 USC § 112***

Claims 1-9, 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preserving cells comprising peripheral blood

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leukocytes and cells suspected of CMV infection wherein pp65 CMV early immediate antigen are detected, does not reasonably provide enablement for preserving antigen presentation on a virally infected mammalian cells wherein at least a portion of which is suspected of being infected with any all types of viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The disclosure does not provide adequate teaching for the broad limitations of claimed invention and a person skilled in that art would be forced into undue experimentations to enable the invention. The specification teaches a method of using protease inhibitors to preserve leukocytes, and cells suspected of being infected by CMV, however, the claimed invention is broadly directed to preserving antigen presenting cells, there is no teaching in the disclosure that any antigen presenting cells have been preserved. The disclosure alludes to detection of pp65 CMV early immediate via staining method. There are no teachings that the CMV antigen was ever presented via MHC I, or MHC II, and whether or not the protease inhibitors preserved the antigen presented mammalian cells. Presentation of antigens into MHC cleft and preservation of cells has to do with mainlining a viable topology of a particular antigen within the MHC cleft. There is no showing in the disclosure that the integrity of MHC structure having a viral antigen has been preserved. The prior art has already taught that the protease inhibitors can extend the shelf life of leukocytes, see Fritz et al (US Patent No. 6,200,969 B1), and Applicants have done the same thing and have preserved leukocytes. There is no teaching that lymphocytes were preserved or any antigen presenting cells were preserved. The state of the art is unpredictable, as Applicants own teaching is testament to the unpredictability of the art (see Example 111). In addition, the disclosure provides no working

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example for the now claimed invention. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-9, 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Warraich et al (Laboratory Investigation, 1/ 2000, Abstract 1398).

The above abstract meets the broad teaching of claimed invention. Warraich et al taught preserving CMV infected cells using protease inhibitors.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Fritz et al (US Patent No. 6,200,969 B1).

The above cited patent taught the a method of increasing survival of cell population including leukocytes (see Figure 6, or 7) utilizing anti-apoptotic reagents wherein the reagents are protease inhibitors including the same the protease inhibitors as now recited having the same formulas and their various permutations (see the claims). Applicants are reminded that cell population of claim 1 of Fritz et al would include viral infected cells, including CMV. The above cited patent taught a general method of preserving cell populations utilizing protease inhibitors, and the teaching and claims of the above cited patent anticipates the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Fritz et al (WO 98/10778 A1).

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The above cited reference taught the a method of increasing survival of cell population including leukocytes (see Figure 6, or 7) utilizing anti-apoptotic reagents wherein the reagents are protease inhibitors including the same formulas and their various permutations (see the claims).

No claims are allowed.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A. R. Salimi

6/29/2004

ALL R. SALIMI  
PRIMARY EXAMINER